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|---|-------------|----------------------|---------------------------|------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 09/932,677 | 08/16/2001 | Donald F. Weaver | 567.1041US1 | 5945 |
| 23280 7590 12/19/2006 DAVIDSON, DAVIDSON & KAPPEL, LLC 485 SEVENTH AVENUE, 14TH FLOOR NEW YORK, NY 10018 | | | EXAMINER RAO, DEEPAK R | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1624 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 12/19/2006 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/932,677

Applicant(s)

WEAVER ET AL.

Examiner

Deepak Rao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION:

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 68, 138, 142 and 145-192 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 68, 138, 142, 145-192 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 68, 138, 142 and 145-192 are pending in this application.

The following rejections are maintained:

1. Claims 68, 138, 142, and 145 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 953,997. The instant claims read on the therapeutic use of the reference disclosed compound. The reference teaches a β -alanine compound, see the structural formula in page 1, and the corresponding therapeutic use of the compound. The reference teaches that the compound showed activity on neurological accident, specifically in a case of epilepsy, see page 3, lines 114-120.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that 'the β -alanine in the reference was administered to an epileptic patient without an intent to treat epilepsy, but rather to the side effects of lysine nicotinate'. The reference however, teaches that β -alanine provides very effective protection against vasomotor or general cutaneous incidents. The reference further teaches the administration of the compound to a case of epilepsy of vascular origin.

Whether administered singly or with another agent, the reference teaches the activity of β -alanine compound. The instant claims recite "comprising" and therefore, do not rule out the possibility of an additional agent.

2. Claims 68, 138, 142, and 145 are rejected under 35 U.S.C. 102(b) as being anticipated by Bey et al., U.S. Patent No. 4,375,477. The instant claims read on the therapeutic use of the

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reference disclosed compound. The reference teaches a substituted β -alanine compound, see the structural formula I in col. 2, and the corresponding therapeutic use of the compound. The reference teaches that the compound is useful in the treatment of central nervous system disorders such as seizure disorders associated with epilepsy, see col. 3, lines 38-43.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that 'the reference cannot anticipate a method of inhibiting epileptogenesis since seizures have already been induced, and the intent of the reference is to treat seizures and not to inhibit epileptogenesis'. The instant claims, however, are drawn to a method of inhibiting epileptogenesis and a method of treatment of convulsive disorder. The reference clearly teaches the use of the compound in, for example, treatment of seizure disorders associated with epilepsy. The reference teaches the administration of the compound to the patient population having seizure disorders which include convulsions and therefore, the method of treatment of the instant claims reads on the reference disclosed method.

3. Claims 68, 138, 142 and 145-186 and new claims 187-192 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 60-99 of copending Application No. 10/272,249.

4. Claims 68, 138, 142, 145, and 151-162 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 60-99 of copending Application No. 11/099,232.

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It is acknowledged that applicants will consider filing of terminal disclaimers upon indication of allowable subject matter.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Monday-Friday from 8:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deepak Rao
Primary Examiner
Art Unit 1624

December 11, 2006